

Applicant : Eric Rose, et al.  
Serial No.: 10/646,493  
Filed : August 21, 2003  
Page 8

**REMARKS**

Claims 1, 9, 13, 14, 19, 20, 23-28, 33 and 34 are pending in the subject application and claims 1, 13, 14, 19, 20, 23-28, 33 and 34 are withdrawn from consideration. Claims 1, 13, 14, 19, 20, 23-28, 33 and 34 have been cancelled as withdrawn. Claim 9 has been amended. Support for the amendment to claim 9 can be found in the specification at, *inter alia*, page 9, lines 1-34 and page 10, lines 19-25. Claims 38-44 have been added. Support for new claim 38 can be found in the specification at, *inter alia*, page 11, lines 31-32. Support for new claim 39 can be found in the specification at, *inter alia*, page 9, lines 16-17. Support for new claim 40 can be found in the specification at, *inter alia*, page 9, lines 18-19. Support for new claim 41 can be found in the specification at, *inter alia*, page 9, lines 19-20. Support for new claim 42 can be found in the specification at, *inter alia*, page 9, lines 20-21. Support for new claim 43 can be found in the specification at, *inter alia*, page 10, lines 27-32. Support for new claim 44 can be found in the specification at, *inter alia*, page 10, lines 32-35 to page 11, lines 1-2. Applicants maintain that the amendment to claim 9 and new claims 38-44 do not raise any issue of new matter. Accordingly, claims 9 and 38-44 will be pending in the subject application upon entry of this Amendment.

**Drawing Objection**

The Examiner objected to Figure 5A because "CaCL" should be "CaCl<sub>2</sub>."

Applicant : Eric Rose, et al.  
Serial No.: 10/646,493  
Filed : August 21, 2003  
Page 9

In response, applicants have amended the application herein by replacing Figure 5A with corrected Figure 5A.

#### **Sequence Rules**

The Examiner objected to the subject application for failing to comply with the requirements of 37 C.F.R. §§1.821-1.825.

In response, applicants annex hereto a paper copy of the Sequence Listing as **Exhibit B**, a Statement in Accordance with 37 C.F.R. §1.821(f) as **Exhibit C**, and a C.R.F. of the Sequence Listing. Applicants have also amended the specification to reflect the SEQ ID NOs. as required by the Examiner.

#### **Objections to the Specification**

The Examiner stated that the applicants must amend the priority claim in order to update the status of two U.S. patent applications.

In response, applicants have amended the priority claim to update the status of the two U.S. patent applications as required by the Examiner.

The Examiner also stated that the term "congenital" appearing on page 6, line 21 is misspelled. In response, applicants have amended the specification to properly spell that term.

#### **Rejections under 35 U.S.C. §102(b)**

The Examiner rejected claim 9 under 35 U.S.C. §102(b) as

Applicant : Eric Rose, et al.  
Serial No.: 10/646,493  
Filed : August 21, 2003  
Page 10

allegedly anticipated by Benedict et al., J. Clin. Invest. 88:1760-1765 ("Benedict"). Specifically, the Examiner stated that Benedict teaches an aqueous saline solution comprising bovine Factor IXa inactivated with Glu-Gly-Arg-chlormethylketone.

In response, applicants respectfully traverse the rejection of claim 9.

Claim 9, as amended, provides a pharmaceutical composition which comprises an effective amount of a Factor IXa compound and a pharmaceutically acceptable carrier, wherein the Factor IXa compound is selected from a group which does not include bovine Factor IXa inactivated with Glu-Gly-Arg-chlormethylketone.

For a reference to anticipate the instant invention, it would have to teach *all the elements thereof*.

Benedict fails to teach each and every element of the claimed composition. Specifically, Benedict fails to teach any Factor IXa compound recited in claim 9. It follows that Benedict does not teach the instant composition. Accordingly, applicants maintain that Benedict fails to anticipate the claimed invention.

The Examiner also rejected claim 9 under 35 U.S.C. §102(b) as allegedly anticipated by Bajaj et al., PNAS 89:152-156 ("Bajaj"). Specifically, the Examiner stated that Bajaj teaches an aqueous composition comprising human Factor IXa inactivated with dansyl Glu-Gly-Arg-chlormethylketone.

Applicant : Eric Rose, et al.  
Serial No.: 10/646,493  
Filed : August 21, 2003  
Page 11

In response, applicants respectfully traverse the rejection of claim 9.

Claim 9, as amended, provides a pharmaceutical composition which comprises an effective amount of a Factor IXa compound and a pharmaceutically acceptable carrier, wherein the Factor IXa compound is selected from a group which does not include human Factor IXa inactivated with dansyl Glu-Gly-Arg-chlormethylketone.

Bajaj fails to teach each and every element of the claimed composition. Specifically, Bajaj fails to teach any Factor IXa compound recited in claim 9, and thus does not teach the instant composition. Accordingly, applicants maintain that Bajaj fails to anticipate the claimed invention.

In view of the above remarks, applicants maintain that claim 9 satisfies the requirements of 35 U.S.C. §102(b).

**Rejections Under 35 U.S.C. §102(a)**

The Examiner rejected claim 9 under 35 U.S.C. §102(a) as allegedly anticipated by Wong et al., Circ. 92:I-686 ("Wong"). Specifically, the Examiner stated that Wong teaches a bolus form of dansyl Glu-Gly-Arg-chlormethylketone-inactivated bovine Factor IXa.

In response, applicants respectfully traverse the rejection of claim 9.

Applicant : Eric Rose, et al.  
Serial No.: 10/646,493  
Filed : August 21, 2003  
Page 12

Claim 9, as amended, is discussed above.

Wong fails to teach each and every element of the claimed composition. Specifically, Wong fails to teach any Factor IXa compound recited in claim 9. Accordingly, applicants maintain that Wong fails to anticipate the claimed invention.

The Examiner also rejected claim 9 under 35 U.S.C. §102(a) as allegedly anticipated by Lenting et al., J. Biol. Chem. 270:14884-14890 ("Lenting"). Specifically, the Examiner stated that Lenting teaches an aqueous composition in which human Factor IXa $\beta$ , i.e. Factor IXa, is reacted with Glu-Gly-Arg-chlormethylketone.

In response, applicants respectfully traverse the rejection of claim 9.

Claim 9, as amended, is discussed above.

Lenting fails to teach each and every element of the claimed composition. Specifically, Lenting fails to teach any Factor IXa compound recited in claim 9. Accordingly, applicants maintain that Lenting fails to anticipate the claimed invention.

In view of the above remarks, applicants maintain that claim 9 satisfies the requirements of 35 U.S.C. §102(a).

#### Summary

For the reasons set forth hereinabove, applicants respectfully

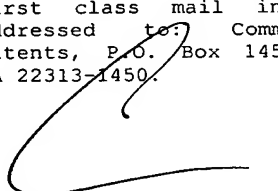
Applicant : Eric Rose, et al.  
Serial No.: 10/646,493  
Filed : August 21, 2003  
Page 13

request that the pending claims of this application be allowed.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the \$60.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
	7/21/05
Alan J. Morrison Reg. No. 37,399	Date

John P. White  
Registration No. 28,678  
Alan J. Morrison  
Registration No. 37,399  
Attorneys for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
Tel. No. (212) 278-0400

Applicant : Eric Rose, et al.  
Serial No.: 10/646,493  
Filed : August 21, 2003  
Page 5

Amendments to The Drawings:

Please replace Figures 5A-B with corrected Figures 5A-B,  
annexed hereto as **Exhibit A**.